at a concentration of at least about 12 mg/ml when said composition is at a temperature of about 4°C; and

(b) a solubilizing compound comprising a guanidinium group, wherein said solubilizing compound is present in said composition in an amount sufficient to make said IGF-I or analogue thereof soluble at a concentration of at least about 12 mg/ml when said composition is at a temperature of about 4°C.

30. The composition of claim 29, wherein said solubilizing compound is guanidine hydrochloride.

Sub D1

31. The composition of claim 29, wherein said solubilizing compound is arginine or an arginine analogue, wherein said arginine analogue is an amino acid analogue of arginine that increases solubility of said IGF-I or analogue thereof at a pH of about 5.5 or greater.

32. The composition of claim 31, wherein said solubilizing compound is arginine.

33. The composition of claim 32, wherein said IGF-I or analogue thereof has an amino acid sequence having at least 95% sequence identity with the amino acid sequence for human IGF-I.

34. The composition of claim 32, wherein said IGF-I is human IGF-I.

35. The composition of claim 34, wherein said arginine is present in a molar concentration range from about 10 mM to about 1 M.

36. The composition of claim 35, wherein said arginine is present in a molar concentration range from about 15 mM to about 500 mM.

9 8
~~37.~~ The composition of claim ~~36~~, wherein said arginine is present in a molar concentration range from about 20 mM to about 200 mM.

10 6
~~38.~~ The composition of claim ~~34~~, wherein said pH is in a range from about pH 5.5 to about pH 9.0.

11 10
~~39.~~ The composition of claim ~~38~~, wherein said pH is in a range from about pH 5.7 to about pH 6.3.

12 11
~~40.~~ The composition of claim ~~39~~, wherein said pH is about pH 6.0.

13 6
~~41.~~ The composition of claim ~~34~~, wherein said IGF-I is present in said composition at a concentration of about 12 mg/ml to about 200 mg/ml.

14 13
~~42.~~ The composition of claim ~~41~~, wherein said IGF-I is present in said composition at a concentration of about 15 mg/ml to about 200 mg/ml.

15 14
~~43.~~ The composition of claim ~~42~~, wherein said IGF-I is present in said composition at a concentration of about 25 mg/ml to about 200 mg/ml.

16 1
~~44.~~ The composition of claim ~~29~~, wherein said composition comprises sodium chloride at a molar concentration of about 150 mM.

17 1
~~45.~~ The composition of claim ~~29~~ comprising a buffer selected from the group consisting of a glutaric acid buffer, a maleic acid buffer, a succinic acid buffer, a citric acid buffer, imidazole, and a histidine buffer.

Sub D2

46. A composition comprising:

(a) biologically active insulin-like growth factor-1 (IGF-I) or biologically active analogue thereof having an amino acid sequence that shares at least 70% sequence identity with the amino acid sequence for human IGF-I, wherein said IGF-I or analogue thereof is present at a concentration of at least about 12 mg/ml when said composition is at a temperature of about 4°C;

(b) a solubilizing compound selected from the group consisting of arginine, an arginine analogue, and guanidine hydrochloride, wherein said arginine analogue is an amino acid analogue of arginine that increases solubility of said IGF-I or analogue thereof at a pH of about 5.5 or greater; and

(c) a buffer such that the composition has a pH of about pH 5.5 to about pH 9.0.

19 18

47. The composition of claim 46, wherein said IGF-I or analogue thereof has an amino acid sequence having at least 95% sequence identity with the amino acid sequence for human IGF-I.

20 18

48. The composition of claim 46, further comprising sodium chloride at a molar concentration of about 150 mM.

49. A method of making an IGF-I composition having a pH of about pH 5.5 to about pH 9.0, said method comprising:

(a) providing an amount of biologically active insulin-like growth factor-1 (IGF-I) or biologically active analogue thereof, such that the IGF-I or analogue thereof is soluble in said composition at a concentration of at least about 12 mg/ml when said composition is at a temperature of about 4°C, said IGF-I or analogue thereof having an amino acid sequence that shares at least 70% sequence identity with the amino acid sequence for human IGF-I; and

(b) combining said IGF-I or analogue thereof with a solubilizing compound comprising a guanidinium group.

50. The method of claim 49, wherein said IGF-I or analogue thereof has an amino acid sequence having at least 95% sequence identity with the amino acid sequence for human IGF-I.

51. The method of claim 49, wherein said solubilizing compound is arginine and wherein said IGF-I is human IGF-I.

52. A method of delivering IGF-I to a vertebrate subject comprising:

(a) providing an IGF-I composition according to claim 29; and

(b) administering said IGF-I composition to said vertebrate subject.

53. The method of claim 52, wherein the administering is parenteral.

54. A method of enhancing the solubility of biologically active insulin-like growth factor-1 (IGF-I) or biologically active analogue thereof in a composition having a pH of about pH 5.5 to about pH 9.0, said IGF-I or analogue thereof having an amino acid sequence that shares at least 70% sequence identity with the amino acid sequence for human IGF-I, said method comprising combining said IGF-I or analogue thereof with an amount of a solubilizing compound that comprises a guanidinium group sufficient to increase the solubility of said IGF-I or analogue thereof relative to the solubility of said IGF-I or analogue thereof in the absence of the solubilizing compound.

55. The method of claim 54, wherein said IGF-I or analogue thereof has an amino acid sequence having at least 95% sequence identity with the amino acid sequence for human IGF-I.

56. The method of claim 55, wherein said solubilizing compound is arginine and wherein said IGF-I is human IGF-I.

57. A method for stabilizing solubility of a biologically active insulin-like growth factor-1 (IGF-I) or analogue thereof within an aqueous solution during freeze-thaw of said solution, said method comprising:

a) preparing said solution; and

b) including arginine or an arginine analogue in said solution in an amount sufficient to stabilize solubility of said IGF-I or analogue thereof within said solution during freeze-thaw relative to the solubility of said IGF-I or analogue thereof in the absence of said arginine or arginine analogue in said solution;

wherein said IGF-I or analogue thereof has an amino acid sequence that shares at least 70% sequence identity with the amino acid sequence for human IGF-I, and wherein said arginine analogue is an amino acid analogue of arginine that increases solubility of said IGF-I or analogue thereof at a pH of about 5.5 or greater.

58. The method of claim 57, wherein said IGF-I or analogue thereof has an amino acid sequence having at least 95% sequence identity with the amino acid sequence for human IGF-I.

59. The method of claim 58, wherein said IGF-I is human IGF-I.

60. The method of claim 59, wherein said IGF-I is soluble in said solution at a concentration of about 7.4 mg/ml when said solution is at about 4°C, and wherein said arginine is present in said solution at a concentration of about 50 mM.

61. A method for stabilizing biological activity of biologically active insulin-like growth factor-1 (IGF-I) or biologically active analogue thereof in a composition during storage of said composition prior to its use, said composition having a pH of about pH 5.5 to about pH 9.0, said method comprising:

a) combining said IGF-I or analogue thereof with an amount of a solubilizing compound comprising a guanidinium group sufficient to increase the solubility of said IGF-I or

analogue thereof relative to the solubility of said IGF-I or analogue thereof in the absence of said solubilizing compound; and

b) storing said composition prior to its use;

wherein said IGF-I or analogue thereof has an amino acid sequence that shares at least 70% sequence identity with the amino acid sequence for human IGF-I.

62. The method of claim 61, wherein said IGF-I or analogue thereof has an amino acid sequence that shares at least 95% sequence identity with the amino acid sequence for human IGF-I.

63. The method of claim 61, wherein said solubilizing compound is arginine or an arginine analogue, wherein said arginine analogue is an amino acid analogue of arginine that increases solubility of said IGF-I or analogue thereof at a pH of about 5.5 or greater.

64. The method of claim 61, wherein said composition is a solution.

65. The method of claim 64, wherein said storing is at a temperature of about 2°C to about 8°C.

66. The method of claim 61, wherein said composition is a freeze-dried composition.

67. The method of claim 66, wherein said storing is at room temperature.

68. A method of preparing a composition comprising biologically active IGF-I or analogue thereof having an amino acid sequence that shares at least 70% sequence identity with the amino acid sequence for human IGF-I, said method comprising preparing a composition according to claim 29.

69. The method of claim 68, wherein said solubilizing compound is guanidine hydrochloride.

70. The method of claim 68, wherein said solubilizing compound is arginine or an arginine analogue, wherein said arginine analogue is an amino acid analogue of arginine that increases solubility of said IGF-I or analogue thereof at a pH of about 5.5 or greater.

71. The method of claim 70, wherein said solubilizing compound is arginine.

72. The method of claim 71, wherein said IGF-I or analogue thereof has an amino acid sequence having at least 95% sequence identity with the amino acid sequence for human IGF-I.

73. The method of claim 71, wherein said IGF-I is human IGF-I.

74. The method of claim 73, wherein said arginine is present at a molar concentration ranging from about 10 mM to about 1 M.

75. The method of claim 74, wherein said arginine is present at a molar concentration ranging from about 15 mM to about 500 mM.

76. The method of claim 75, wherein said arginine is present at a molar concentration ranging from about 20 mM to about 200 mM.

77. The method of claim 73, wherein said pH is in a range from about pH 5.5 to about pH 9.0.

78. The method of claim 77, wherein said pH is in a range from about pH 5.7 to about pH 6.3.